UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. BIOVAIL CORPORATION, EUGENE MELNYK, BRIAN CROMBIE, JOHN MISZUK, and KENNETH HOWLING, Defendants.	No. 08-cv-02979 (LAK) (GWG) ECF Case

DEFENDANT BRIAN CROMBIE'S MEMORANDUM OF LAW IN SUPPORT OF HIS MOTION TO DISMISS UNDER FED. R. CIV. P. 9(b) OR, IN THE ALTERNATIVE, FOR A MORE DEFINITE STATEMENT UNDER FED. R. CIV. P. 12(e)

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Defendant Brian Crombie respectfully submits this memorandum of law in support of his motion to dismiss the complaint under Fed. R. Civ. P. 9(b) for failure to allege facts that give rise to a strong inference of scienter or to plead fraud with particularity or, in the alternative, for a more definite statement under Fed. R. Civ. P. 12(e).

PRELIMINARY STATEMENT

The Securities and Exchange Commission ("SEC") has been investigating this matter for over four (4) years. During that span, the SEC, in concert with its Canadian counterpart, the Ontario Securities Commission ("OSC"), has subpoenaed millions of pages of documents and compelled testimony from dozens of deposition witnesses, including Mr. Crombie, who appeared before the SEC to testify on three occasions. Yet despite the SEC's far-reaching and lengthy investigation, which encompassed discovery well beyond that which would have been permitted by the Federal Rules of Civil Procedure, its complaint (attached as Exhibit A to the Chen Decl.) still falls well short of the basic pleading standards required for cases alleging fraud. See Fed. R. Civ. P. 9(b).

The gist of the SEC's complaint is that Mr. Crombie and others allegedly made false statements or caused their company, Biovail Corporation, Inc. ("Biovail"), to make false statements to the investing public and to the company's independent auditors. In so doing, the complaint repeatedly bandies about the words "fraud," "sham," and "phony," and, on numerous occasions, makes the broad assertion that Mr. Crombie "knew" or "recklessly disregarded" that certain representations or financial statements were "materially false and misleading." Stripping away those pejoratives and conclusory allegations, however, one finds a paucity of concrete facts to support the SEC's claims of fraud.

With respect to the alleged PharmaTech and bill-and-hold transactions, see Compl. ¶¶ 49-82, 83-124, the complaints fails to plead facts demonstrating a "strong inference of scienter." See ATSI Comm., Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007); SEC v. Collins & Aikman Corp., 524 F. Supp. 2d 477, 488 (S.D.N.Y. 2007) ("the SEC is subject to Rule 9(b) and must therefore plead a 'strong inference' of scienter"). The SEC alleges no facts to indicate that Mr. Crombie had a concrete "motive and opportunity" to commit fraud. Nor does the complaint contain "strong circumstantial evidence" of conscious misbehavior or recklessness on his part.

With respect to its claims of false and misleading statements allegedly made to Biovail's independent auditors, see Compl. ¶¶ 69-71 (alleging misstatements in connection with the PharmaTech transaction), 118-24 (alleging misstatements in connection with the bill-and-hold sale), 165-68 (Fifth Claim for Relief), the complaint suffers from another basic deficiency. It fails to state with particularity the circumstances constituting the fraud. There is no description of "who" the purportedly false statements were made to, "when" they were made, "where" they were made, or "why" those alleged statements or omissions caused the auditors to be misled. See Mills v. Polar Molecular Corp., 12 F.3d 1170, 1175 (2d Cir. 1993) (holding that Rule 9(b) requires a complaint to "specify the statements that the plaintiff contends were fraudulent," "state where and when the statements were made," and "explain why the statements were fraudulent"). Mr. Crombie should not be required to guess.

Because the SEC fails to allege facts that give rise to a strong inference of scienter or to plead fraud with particularity as required by Rule 9(b), the complaint should be dismissed or, in the alternative, the SEC should be compelled to make a more definite statement.

FACTUAL BACKGROUND[1]

Biovail is a publicly traded pharmaceutical company based in Canada. Compl. ¶ 1. During the relevant period, from May 2000 to August 2004, Mr. Crombie served as Biovail's Chief Financial Officer ("CFO") and, from August 2004 to May 2007, he was Senior Vice President of Strategic Development. Compl. ¶ 14. The SEC does not allege that Mr. Crombie is a certified public accountant in the United States or a chartered accountant in Canada. Nor does the SEC claim that Mr. Crombie has any specialized training in U.S. (or Canadian) generally accepted accounting principles ("GAAP").

The SEC's complaint asserts that Mr. Crombie, individually or in concert with others, was involved in three separate matters that were the subject of false or misleading statements regarding Biovail's financial results: (1) public statements regarding a shipment of Wellbutrin XL that was involved in a fatal truck accident on October 1, 2003 and its effect on Biovail's reported revenue for the third quarter of 2003, Compl. ¶¶ 17-48; (2) an alleged failure to record expenses and liabilities in 2001 and 2002 incurred by a separate entity, Pharmaceutical Technologies, Inc. ("PharmaTech"), which conducted research and development on six Biovail drugs, id. ¶¶ 49-82; and (3) Biovail's recognition of revenue from the sale of Wellbutrin XL to a Distributor through a "bill and hold" arrangement in the second quarter of 2003, id. ¶¶ 83-124.[2] This motion addresses the insufficiency of the SEC's allegations regarding the PharmaTech transaction and the bill-and-hold sale.

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[1] For purposes of this motion to dismiss, well-pleaded facts in the complaint are assumed to be true, see In re NYSE Specialists Sec. Litig., 503 F.3d 89, 95 (2d Cir. 2007); however, this Court need not accord "[l]egal conclusions, deductions or opinions couched as factual allegations . . . a presumption of truthfulness." Id. The Court "may [also] consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." ATSI, 493 F.3d at 98.

[2] The SEC also makes allegations concerning two other matters unrelated to Mr. Crombie – purported material misstatements regarding an unrecognized foreign exchange loss and the alleged failure of another executive to disclose properly his share ownership in the company. Compl. ¶¶ 125-46.

As an initial matter, the complaint attempts at the outset to explain Mr. Crombie's and others' alleged motive to engage in fraud. The SEC claims that Biovail's executives were "[o]bsessed with meeting quarterly and annual earnings guidance" and that, in the second quarter of 2003 in particular, "the Company was in danger of missing earnings expectations for the first time in its history." Compl. ¶¶ 1, 83. There is no allegation, however, that Mr. Crombie was motivated by any sort of personal or pecuniary gain. The SEC does not claim that Mr. Crombie sold any of his Biovail shares at inflated prices or that his compensation or career advancement was tied in any way to the success of the purported frauds. In short, the complaint is devoid of any suggestion that Mr. Crombie received a concrete benefit as a result of his alleged misconduct.

A. The PharmaTech Transaction

In mid-2001, Biovail created a special purpose entity known as PharmaTech to handle the research and development ("R&D") for six of its pipeline products. Compl. ¶ 49. Biovail did not own PharmaTech, however; its sole shareholder was another individual. Id. ¶ 50. All costs associated with the R&D were to be paid for by PharmaTech, which could use funds drawn from a line of credit between PharmaTech and the Bank. Id. ¶¶ 57, 66. The PharmaTech loan was subject to annual renewal, which the Bank could grant or deny in its sole discretion. Id.

In order to permit PharmaTech to conduct the R&D, Biovail licensed certain proprietary technology to PharmaTech "to develop the [six] products." Compl. ¶¶ 57, 66. If the R&D were successful and led to an FDA-approved drug, then Biovail would pay a royalty to PharmaTech based on a percentage of net sales over ten years. Id. ¶ 58. In addition, depending on future developments, Biovail had an option to purchase PharmaTech outright by paying a lump sum to

PharmaTech's sole stockholder in exchange for all of his shares. Id. ¶ 63. That lump sum ranged from $1.25 million to $5 million, depending on when the option was exercised. Id.

Such arrangements are not unusual, and U.S. GAAP expressly provides that, depending on various factors, a party (such as Biovail) that participates in an R&D arrangement through which it can obtain the results of R&D funded entirely by others (such as PharmaTech or the Bank lending funds to PharmaTech) is not required to record those R&D expenses on its own books and records. See Compl. ¶¶ 54-56 (discussing Statement of Financial Accounting Standards 68 ("FAS 68")).

One critical factor under FAS 68 is whether the party (i.e., Biovail) is obligated to repay any of the R&D funds provided by the other parties (i.e., PharmaTech or the Bank as its principal creditor) "regardless of the outcome of the research and development." Id. In other words, the question is whether the expenses properly belong to PharmaTech alone or should instead be attributable to Biovail. In this case, the SEC alleges that the requirements of FAS 68 were not met and that Mr. Crombie and Biovail deliberately failed to include PharmaTech's expenses and liabilities as Biovail's own, thereby distorting Biovail's financial statements related to the third quarter of 2001 through the year-end of 2002. Id. ¶¶ 53, 74-82.

The difficulty with the SEC's theory, however, is that Mr. Crombie expressly consulted with Biovail's independent auditors concerning the PharmaTech transaction to ensure that the company's proposed accounting treatment was permissible under FAS 68. Compl. ¶ 69. The auditors provided a written opinion to that effect, namely, that Biovail was not required to reflect PharmaTech's expenses and liabilities on its own financial statements. Id. (discussing opinion letter); see also Letter from Ernst & Young LLP to Mr. Brian Crombie dated June 29, 2001 (attached as Exhibit B to the Chen Decl.). In so doing, the independent auditors reviewed drafts

of all the relevant agreements between Biovail and PharmaTech and PharmaTech and the Bank. Id. There is no allegation that any of those papers were doctored or falsified in any way.

In order to avoid the clear import of the auditor's opinion letter – which would be to negate any scienter on the part of Mr. Crombie – the SEC alleges that Mr. Crombie made various misstatements to one or more unnamed auditors. In particular, the SEC asserts that:

- Crombie told the auditors that Biovail's management did not believe that it was probable that Biovail would repay the amounts being advanced [regardless of the outcome of the R&D] and that the funding provided by others should not be recorded as a liability.

- Crombie told the auditors that Biovail had not provided any explicit or implicit undertakings to any parties involved in the transaction to repay all or a portion of the funds provided.

- Crombie told the auditors that Biovail's management did not currently believe that it was probable that it would choose to purchase the common shares of PharmaTech rather than incur any penalty [associated with the potential transfer of its proprietary technology to a third party].

Compl. ¶ 70.[3]

The complaint then makes the blanket assertion that those statements were "materially false and misleading." Compl. ¶ 71. No further explanation is provided. Notably, the complaint does not point to any facts that would show Mr. Crombie's statements were factually incorrect, or that he knew them to be untrue. There is no allegation that Biovail's management did in fact "believe that it was probable that Biovail would repay the amounts being advanced" by the Bank

[3] It is unclear when, where, or to whom in particular these purported misstatements were made. The complaint does not provide any particulars. While only speculation, it appears that the SEC might have taken the alleged representations from various snippets contained in the auditor's opinion letter, in particular, from a section entitled "Application to these facts." Compare Compl. ¶¶ 69-70 with Exhibit B, at 5-7 (stating "You have informed us that . . ." or "It is our understanding that . . ."). The principal purpose of Rule 9(b), of course, is that Mr. Crombie should not have to guess. Nonetheless, proceeding on that assumption, because the opinion letter first lists the various factors mentioned in FAS 68 and then separately discusses their application to the PharmaTech transaction, it is necessary to include the bracketed language to place the SEC's snippets into their proper context.

regardless of the outcome of the R&D. (Indeed, if the R&D were unsuccessful, it would be contrary to the company's financial self-interest to exercise an option to acquire a failed endeavor and become obligated to repay its debts.) Nor does the SEC claim that Biovail had in fact "provided [an] explicit or implicit undertaking" to the Bank to repay all or a portion of the funds. And there is no contention that Biovail's management did in fact "currently believe that it was probable that it would choose to purchase the common shares of PharmaTech rather than incur any penalty."

At most, the SEC attempts to draw an inference of fraud by juxtaposing Mr. Crombie's alleged statements to the auditors with his purported oral conversations with the Bank. Compl. ¶¶ 68, 71. In particular, the SEC claims that Mr. Crombie failed to tell the auditors what he had told the Bank, namely, that: (1) "in the event of a PharmaTech default, Biovail would have a compelling business incentive to exercise its option to acquire PharmaTech"; (2) "that the annual loan renewal was effectively an 'annual put' to Biovail"; and (3) that "Biovail would not want to see the technology license [to PharmaTech] fall into the hands of Biovail's competitors." Id. ¶ 71.[4]

Based on the facts alleged, however, there is no inherent inconsistency between these two sets of alleged statements. Rather than leap to conclusions of fraud, the more plausible inference is that Mr. Crombie's statements to the Bank were nothing more than a description of the obvious considerations one could deduce from reviewing the contractual documents (all of which were fully shared with the auditors). First, by looking at the royalty provision and the option provision together, one could discern that, if PharmaTech defaulted, then Biovail might have a

[4] Again, there is no description as to when, where, or to whom in particular these purported statements to "the Bank" were made. There is not even an indication whether all three statements were made during a single discussion with one Bank employee or in multiple discussions with different ones.

"compelling business incentive" to exercise its option to acquire PharmaTech – but if and only if the cost of making royalty payments exceeded the cost of purchasing PharmaTech outright. There is no allegation, however, that the royalty rates and option costs were deliberately structured to ensure that disparity, or that Mr. Crombie expected that to be the case.

Second, by looking at the line of credit provision and the annual renewal mechanism, it was plain that, by placing renewal of the loan in jeopardy each year, the Bank could oblige Biovail to consider the above cost-benefit analysis. That might be construed "effectively" as an "annual put" – but if and only if Biovail were further compelled in fact to exercise that purchase option. There is no allegation, however, that Biovail was required to do so; and, if PharmaTech's R&D appeared unpromising, Biovail was always free to walk away from the transaction and let PharmaTech default.

Third, by looking at the licensing provision (or simply using common sense), it was evident that Biovail "would not want to see the technology license fall . . . into the hands of [its] competitors." And that might encourage Biovail to exercise its option to acquire PharmaTech – but if and only if those competitors were then expected to breach the license's terms and unlawfully convert Biovail's technology for their own uses (rather than to develop the six Biovail products). See Compl. ¶ 66 (describing the Bank's security interest in the license to use the Biovail technology "to develop the products" – not for general usage). There is no allegation, however, that Biovail's competitors were prepared to engage in the unlawful conversion of Biovail's intellectual property, or that Mr. Crombie expected that to be the case.

Importantly, all of these points that Mr. Crombie allegedly communicated to the Bank were not concealed from the auditors, but were in fact expressly considered by them. See Exhibit B. The auditors noted that PharmaTech would own the royalty rights and that Biovail "could simply

manufacture and market the products and pay the royalty," rather than exercise its purchase option and repay the Bank. Id. at 6-7. The auditors also understood that the annual renewal mechanism meant that the "lender makes annual decisions on additional tranches of funding," which placed the continuation of PharmaTech's R&D in potential jeopardy each year. Id. And the auditors recognized that PharmaTech "does not and will not own any 'core technology,'" id. at 7, and thus PharmaTech's ability to use that technology for purposes "other than the development of the products stipulated" was "limited," id. at 2.

In the end, the auditors noted that this was "an area of significant management judgment." Id. at 7. In other words, given the complexity and unpredictability of so many different variables, GAAP did not compel a definitive conclusion one way or the other. See Thor Power Tool Co. v. Commissioner, 439 U.S. 522, 544, 99 S. Ct. 773, 787 (1979) (stating that GAAP is not a "canonical" set of rules, but rather "tolerate[s] a range of 'reasonable' treatments, leaving the choice among alternatives to management"). Given this permissible range of reasonable accounting treatments, the complaint must allege facts to show that Mr. Crombie exercised his judgment in an intentional and fraudulent violation of GAAP. This it does not do.

B. The Bill-and-Hold Sale of Wellbutrin XL in the Second Quarter of 2003

In October 2001, Biovail and the Distributor entered into a Development, License and Copromotion Agreement (the "Agreement") under which Biovail agreed to manufacture Wellbutrin XL ("WBXL") for the Distributor, which would then distribute the product to third-party purchasers. Compl. ¶ 84. Under the Agreement, Biovail would sell identical pills to the Distributor under two different pricing structures: (1) "sample" product, which the Distributor would provide to doctors to be given to patients as a promotional tool, and (2) "trade" product, which the Distributor would sell at a commercial price. Id. Biovail would be paid for sample

pills at cost and for trade pills at a fixed percentage of the Distributor's net sales revenues. Id. ¶ 85.

The actual distribution of WBXL was contingent on the product receiving formal FDA approval, which was still pending as of mid-2003. See Compl. ¶ 86. In April and May 2003, however, the Distributor requested that Biovail begin manufacturing WBXL tablets even before formal FDA approval had been granted, so that the Distributor would have sufficient supplies of product on hand in anticipation of an immediate full-scale launch. Id. ¶¶ 90-91. Yet Biovail had no incentive to produce WBXL pills solely for sale as sample product, since filling sample orders would take up Biovail's limited manufacturing capacity without generating any incremental income. Id. ¶ 92.

Accordingly, in June 2003, the Distributor agreed to place an order for trade product that was based on a fixed price, with no possibility of downward reconciliation. Compl. ¶¶ 93-94 (discussing June 19, 2003 letter from Mr. Crombie to the Distributor); Letter from Mr. Brian Crombie to Mr. Stan Hull dated June 19, 2003 (attached as Exhibit C to the Chen Decl.) ("[The CEO of the Distributor] agreed that there should be no downward reconciliation on price."). The negotiations leading up to that order were documented in Mr. Crombie's June 19, 2003 letter. Id. (stating that "in June of 2002, representatives of Biovail had a meeting with [the Distributor], at which we discussed Biovail's requirement to ship trade supplies of WBXL to you in Q2 of 2003. . . . It was our understanding that we had verbally agreed both on the timing of those shipments and the pricing of the product . . . ."). The next day, the Distributor issued a firm purchase order for 27.1 million tablets of trade product. Compl. ¶ 95.

As of late June 2003, Biovail had approximately 18 million pills of trade product that were fully manufactured. Compl. ¶ 95. The SEC does not allege that these were non-existent or

phantom pills. Since FDA approval was still pending, however, Biovail could not label the final packaging, so "the Distributor agreed to let Biovail hold the product" awaiting final FDA approval. Id. Thus, instead of shipping the pills to the Distributor, Biovail earmarked and segregated the pills in its warehouse and, on June 30, 2003, invoiced the Distributor for the sale of the trade pills. Id. ¶¶ 95-96, 100. Biovail then recognized the revenue associated with that sale in its financial statements and other disclosures related to the second quarter of 2003. Id. ¶¶ 106-17.[5]

The SEC acknowledges that, under U.S. GAAP, a company may properly recognize revenue from a bill-and-hold arrangement if certain criteria are met. See Compl. ¶¶ 97-99 (discussing Staff Accounting Bulletin No. 101 ("SAB 101")).[6] In this case, the SEC contends that two of those requirements were violated in that (1) there was no "fixed schedule for delivery," since the date of final FDA approval was not yet known as of June 30, 2003, id. ¶ 96, and (2) Biovail had not segregated the ordered goods from its inventory and precluded them from being used to fill other orders, id. ¶¶ 100-01. The complaint then makes the conclusory assertion that Mr. Crombie "knew, or recklessly disregarded, that the requirements for U.S. GAAP . . . were not satisfied." Id. ¶ 107. Based on the facts alleged, however, there is no basis for such an inference of scienter (much less a strong one).

First, even assuming as a factual matter that U.S. GAAP requires a "fixed schedule for delivery" to mean only a "fixed calendar date" and not a "fixed occurrence," the SEC does not

[5] We understand the SEC is alleging that the 18 million pills should not have been classified as trade product as of June 30, 2003. Assuming, however, that classification was correct, there is no allegation that the revenue associated with those trade pills ($8 million) was inflated.

[6] According to the SEC, those requirements are: (a) the risk of ownership has transferred to the buyer, (b) the customer has made a fixed commitment to buy the goods, (c) the buyer requests that the transaction be completed on a bill and hold basis, (d) there is a fixed schedule for delivery of the goods to the buyer, (e) the seller has not retained any specific performance obligations, (f) the ordered goods have been segregated from the seller's inventory and not used to fill other orders, and (g) the goods are complete and ready for shipment. Compl. ¶¶ 98-99.

allege that Mr. Crombie was aware of that "interpretive" limitation. The more plausible inference is that Mr. Crombie, as a non-accountant who had no specialized knowledge of SAB 101, would read that phrase to include a fixed occurrence, such as the granting of final FDA approval.

Second, the SEC fails to allege that the 18 million trade pills that were in existence as of June 30, 2003 were not "segregated" or were in fact somehow commingled with Biovail's other inventory. Instead, what the SEC seems to allege is that Mr. Crombie knew that the 18 million tablets (which were segregated) were not the "ordered goods" – in the sense that those pills were inherently unsuitable as trade product. The SEC alleges that Mr. Crombie knew in June that "all of the tablets . . . were already at that time too old for trade use." Compl. ¶ 101. That contention is squarely contradicted, however, by the SEC's own allegation (indeed, in the same sentence) that "no one knew prior to FDA approval what the expiration for trade product would be." Id. (emphasis added). If "no one" (a category that, by definition, would include Mr. Crombie) knew when the trade pills would become stale, then it cannot be that, on June 30, 2003, Mr. Crombie knew that all 18 million tablets were already too old.[7]

Third, with respect to the alleged "pills switch" – whereby the segregated trade pills were "designated" in July 2003 for shipment as sample pills and replaced by newer pills, Compl. ¶¶ 101-05 – the SEC does not allege that such "designation" took place before June 30, 2003. See id. ¶¶ 100 (alleging that sample designation occurred "very soon thereafter" June 30), 101 (alleging that sample designation occurred "no later than mid-July"). In other words, as of the June 30 quarter-close, all of those 18 million pills were properly allocated as trade product. The

[7] In addition to defying logic, the SEC's allegations also run counter to common sense. It would be highly unusual for "all of the pills" (especially those manufactured in late June) to have become "too old" by June 30. That would mean that some pills became stale within a matter of days.

pills switch only arose afterwards – and, so long as the pills were switched out by the time the now-sample pills were shipped from the warehouse in August 2003 (which was Mr. Crombie's expectation), id. ¶ 102, 111, there would always be 18 million trade tablets remaining in the segregated section, ready for delivery as trade.[8] The complaint does not allege that U.S. GAAP expressly prohibits such a product switch. Nor is there any allegation that Mr. Crombie was informed or aware that, under U.S. GAAP, the pills switch would cause a post hoc change to the accounting for the bill-and-hold sale.

Fourth, the SEC claims that Mr. Crombie made various material misstatements and omissions about the bill-and-hold sale to the company's independent auditors. Compl. ¶¶ 118-24. In particular, the complaint alleges that, during the quarterly review for the second quarter of 2003, Mr. Crombie failed to correct the auditors' misunderstanding that the sale was a "shipment" rather than a bill-and-hold transaction and failed to inform the auditors about the pills swap. Id. ¶¶ 120, 123. There is no allegation, however, that the auditors raised any specific questions to Mr. Crombie that would have prompted him to provide the omitted details, or that he somehow knew he was obliged to apprise the auditors of that information. In the absence of

[8] The SEC's allegations – that there were insufficient replacement pills as of June 30 or as of mid-July when the "designation" occurred – are beside the point. Compl. ¶¶ 102, 105, 107. There is no allegation that Biovail recognized any sample revenue on the date of "designation." So there is no issue with the same pills being "sold" twice – one of the principal evils that the bill-and-hold guidance was designed to redress. In the absence of any contrary allegation, presumably, the sample revenue was recognized when the now-sample pills were shipped. So long as there were still 18 million trade tablets – as of those shipment dates in August 2003 – segregated in the warehouse, the understanding was that GAAP did not require the bill-and-hold revenue to be adjusted post-quarter close.

For the same reason, the various mix-ups with the June and August invoices are irrelevant. Biovail issued invoices in June 2003 at trade prices associated with the 18 million (then-trade) pills. Compl. ¶ 96. After the pills switch occurred, when the now-sample product was shipped in August 2003, Biovail issued additional invoices associated with those same (now-sample) pills. Compl. ¶ 111. That this caused the Distributor some confusion is understandable. All that needed to be done, however, was to amend the June invoices with an updated reference to the new trade pills (which remained segregated in the Biovail warehouse awaiting FDA approval). And this is essentially what occurred when Biovail issued two credit memos cancelling the June invoices and then re-issued new invoices with the updated information. Compl. ¶¶ 115, 124. In the end, there is no allegation that Biovail attempted to double-bill the Distributor. At all times, there was only one set of invoices for the trade sale in June and one set of invoices for the sample sale in August.

such an allegation, it is more plausible to infer that Mr. Crombie simply did not perceive those facts to be critical.[9] In addition, the SEC alleges that, during the year-end review for 2003, Mr. Crombie misled the auditors about the Distributor's refusal to pay the original June invoices and the need for Biovail to issue "credit memos" cancelling those invoices (which were later re-issued with updated information for the new trade pills). Id. ¶¶ 121, 124. The complaint fails to allege, however, that Mr. Crombie was involved in the issuance of the credit memos, id. ¶ 115, or that he had been told of the alleged "true" reason why they were issued. Accordingly, none of Mr. Crombie's statements to the auditors can give rise to an inference of scienter.

ARGUMENT

I. THE COMPLAINT MUST BE DISMISSED BECAUSE THE PLAINTIFF FAILS TO ALLEGE FACTS THAT GIVE RISE TO A STRONG INFERENCE OF SCIENTER

Under Rule 9(b), any complaint that sounds in fraud must allege facts giving rise to a "strong inference of scienter." ATSI Comm., Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). This requirement applies equally to the SEC as well as to private plaintiffs. See SEC v. Collins & Aikman Corp., 524 F. Supp. 2d 477, 488 (S.D.N.Y. 2007) ("the SEC is subject to Rule 9(b) and must therefore plead a 'strong inference' of scienter"); see also SEC v. Durgarian, 477 F. Supp. 2d 342, 353 (D. Mass. 2007) ("the SEC must also set forth facts giving rise to a 'strong inference' that the defendants acted with the required state of mind") (internal quotations omitted); SEC v. Boling, No. 06 Civ. 1329, 2007 WL 2059744, at *6 (D.D.C. July 13, 2007).

[9] Notably, even after Biovail's independent auditors became aware of the bill-and-hold accounting, the lack of a fixed calendar date, and the pills switch, they have not required Biovail to restate its financial statements from the second quarter of 2003 to remove the bill-and-hold revenue. That fact tends to negates any inference of fraudulent intent. See Druskin v. Answerthink, Inc., 299 F. Supp. 2d 1307, 1323 & n.25, 1326-27 (S.D. Fla. 2004) (stating that any inference of scienter was refuted because, among other things, there were "no restatements or auditor resignations").

In order to qualify as "strong," the inference of scienter "must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling, thus strong in light of other explanations." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. ---, 127 S. Ct. 2499, 2510 (2007) ("a court must consider plausible nonculpable explanations for the defendant's conduct").[10]

As a general matter, a strong inference of scienter may be shown only where there are well-pleaded facts either (1) demonstrating that Mr. Crombie had the "motive and opportunity" to commit fraud, or (2) constituting "strong circumstantial evidence" of conscious misbehavior or recklessness. See Collins & Aikman, 524 F. Supp. 2d at 487. Conclusory allegations of fraudulent intent are wholly insufficient. Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1129 (2d Cir. 1994).

A. The Complaint Does Not Allege that Mr. Crombie Had the Motive and Opportunity to Commit Fraud

To demonstrate "motive and opportunity" sufficient to satisfy Rule 9(b), the SEC must allege that the fraud was expected to lead to "concrete benefits" for the defendant. See Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). "Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." Id. Non-concrete motives, such as "the desire for the corporation to appear profitable" or "the desire to keep stock prices high to increase officer compensation" are inadequate. Id. Such allegations are "common to all corporate executives and, thus, too generalized to demonstrate scienter." Id.

[10] Although the Supreme Court in Tellabs was addressing the statutory "strong inference" provision in the PSLRA, its general discussion on how to weigh the strength of an inference applies equally here under Rule 9(b). See Boling, 2007 WL 2059744, at *9.

In this case, the SEC only sets forth generalized assertions regarding Mr. Crombie's alleged desire for Biovail meet earnings targets. Compl. ¶¶ 1, 83. These allegations are no different from the ones previously rejected by the Second Circuit as insufficient. See Kalnit, 264 F.3d at 139. There is no claim of any stock sales at inflated prices or any connection between Mr. Crombie's compensation and the success of the purported fraud. Thus, the SEC cannot meet its obligations under Rule 9(b) through the "motive and opportunity" prong. See In re Northern Telecom Ltd. Sec. Litig., 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("The absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders' expense, is inconsistent with an intent to defraud shareholders.").

B. The Complaint Does Not Allege Sufficient Facts Showing Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

In the alternative, the SEC may show a "strong inference" of scienter by pointing to "strong circumstantial evidence" that Mr. Crombie engaged in fraudulent or reckless misconduct. Yet where (as here) "motive is not apparent . . . the strength of the circumstantial allegations must be correspondingly greater." Kalnit, 264 F.3d at 142. "At the least," the SEC must point to "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Id. (emphasis added) (internal quotations omitted).

Even clear violations of U.S. GAAP alone do not establish that the defendant acted with the requisite intent to defraud. See In re BISYS Sec. Litig., 397 F. Supp. 2d 430, 448 (S.D.N.Y. 2005) (Kaplan, J.). This is because an innocent misapplication of complex accounting principles, rather than deliberate deceit, is just as likely, if not more likely, to be the cause.

Finally, boilerplate allegations of scienter – for example, that the defendant "'knew but concealed' some things or 'knew or were reckless in not knowing' other things" – are insufficient to withstand dismissal under Rule 9(b). See Shields, 25 F.3d at 1129. Such allegations are "so broad and conclusory as to be meaningless." Id.; see also Decker v. Massey-Ferguson, Ltd., 681 F.2d 111, 121 (2d Cir. 1982) ("conclusory allegations that defendant's conduct was fraudulent or deceptive are not enough"). In this case, after putting aside the SEC's repeated "conclusory" and "meaningless" allegations, see, e.g., Compl. ¶¶ 74, 75, 76, 80, 82, 101, 107, 110, 112, 114, 116, 117, one is left with a paucity of actual facts to support an inference of scienter.

Regarding the PharmaTech transaction, the SEC's complaint boils down to an alleged divergence between the statements that Mr. Crombie purportedly made to the auditors versus what he supposedly said to the Bank. As explained above, however, see pp. 7-9, supra, that divergence is mostly illusory. It is clear from the complaint's description of the relevant contracts that there were numerous variables that might provide differing incentives or disincentives for Biovail to exercise its option to acquire PharmaTech and repay the Bank. It all depended upon one's assumptions at any given point in time about the expected success of the R&D, the expected market for any approved drugs, the expected cost of paying royalties over a ten-year span, the expected cost of exercising Biovail's purchase option, and other inchoate factors, such as the likelihood that a third-party acquirer of PharmaTech might unlawfully convert Biovail's technology for some unlicensed use.

The auditors were aware of these competing considerations. See Exhibit B, at 7 ("This is an area of significant management judgment."); cf. Thor Power Tool, 439 U.S. at 544, 99 S. Ct. at 787 ("[GAAP] tolerate[s] a range of 'reasonable' treatments, leaving the choice among

alternatives to management."). And the more plausible inference is that Mr. Crombie was simply discussing those same considerations with the Bank – namely, that, under certain circumstances, Biovail might face compelling reasons to exercise its purchase option. Nevertheless, the complaint fails to allege that Mr. Crombie had reached a fixed or even probable determination that Biovail would in fact exercise that option regardless of the outcome of the R&D. In the absence of that allegation, there is no basis to infer that Mr. Crombie was deliberately hiding something that the auditors did not already know.

Regarding the bill-and-hold sale, any strong inference of scienter must rise or fall on the implications to be drawn from the SEC's two alleged violations of SAB 101. As explained above, however, see pp. 11-14, supra, the facts do not show that Mr. Crombie intentionally or even recklessly violated U.S. GAAP. First, with respect to the "fixed schedule for delivery": Even assuming that Mr. Crombie knew there was no "fixed date" but only a "fixed event," and further assuming that U.S. GAAP only permits the first and not the second (a dubious assumption that the SEC will be hard-pressed to prove at trial), the complaint still fails to allege facts showing that Mr. Crombie deliberately or recklessly ignored that bit of GAAP arcana. It is far more plausible that any alleged breach of that supposed prerequisite was the result of an inadvertent and innocent misunderstanding of U.S. GAAP by a non-accountant.

Second, with respect to the "ordered goods" being "segregated" and not being subject to fill other orders: The SEC does not allege that the 18 million trade pills in existence in late June were unsegregated, or that Mr. Crombie was informed that was the case. Moreover, the allegation that Mr. Crombie somehow knew that all 18 million tablets were "already too old for trade use" is contradicted by the SEC's own statement that "no one" knew "what the expiration date for trade product would be." Compl. ¶ 101 (emphasis added). Thus, the facts strongly

indicate that, as of June 30, 2003, the 18 million trade pills were firmly and properly designated as trade product. The fact that the pills switch took place does not undermine that inference.[11] The complaint does not allege that U.S. GAAP prohibits a one-for-one switch of product being held as part of a bill-and hold transaction. And even if there were, there is no reason to infer that Mr. Crombie was aware of any such prohibition.

II. THE COMPLAINT MUST BE DISMISSED BECAUSE THE PLAINTIFF FAILS TO PLEAD FRAUD WITH SUFFICIENT PARTICULARITY UNDER FED. R. CIV. P. 9(b)

In addition to requiring facts that demonstrate a "strong inference" of scienter, Rule 9(b) also demands that allegations of fraud must be stated "with particularity" in respect of the circumstances constituting the fraud. Fed. R. Civ. P. 9(b). To satisfy the "particularity" requirement, the complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Mills v. Polar Molecular Corp., 12 F.3d 1170, 1175 (2d Cir. 1993). Moreover, where the SEC contends that a defendant "had access to contrary facts," the complaint must "specifically identify the reports or statements containing this information." Collins & Aikman, 524 F. Supp. 2d at 485 (quoting Novak v. Kasaks, 216 F.3d 300, 309 (2d Cir. 2000)); accord Goplen v. 51job, Inc., 453 F. Supp. 2d 759, 770 (S.D.N.Y. 2006) (stating that boilerplate allegations of scienter are insufficient where plaintiffs "fail to identify any documents . . . or reports that show that defendants knew or should have known" about contrary information).

[11] The SEC's reliance on later events, such as the pills switch or the updated invoices, to infer that this "must" have been what Mr. Crombie intended all along is precisely the sort of "fraud by hindsight" that has been rejected by courts. See Shields, 25 F.3d at 1129 (rejecting notion of "fraud by hindsight"); Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978).

Regarding both the PharmaTech and bill-and-hold transactions, the SEC alleges that Mr. Crombie made various false or misleading statements to the company's independent auditors. Compl. ¶¶ 69-71, 118-24, 165-68. Yet, in each instance, the complaint is mysteriously devoid of the basic particulars of "when" or "where" the purported misstatements were made and "to whom" they were uttered. In order to satisfy Rule 9(b), the SEC must allege that (1) on or about a certain date, Mr. Crombie spoke (2) with a particular person or persons and (3) made the following misstatements, which were untrue, because (4) Mr. Crombie had been informed to the contrary by the following communication. Compare Compl. ¶¶ 69-71, 118-24 with SEC v. Blackwell, 291 F. Supp. 2d 673, 690 (S.D. Ohio 2003) (holding that complaint satisfied Rule 9(b) where it alleged that defendant disclosed material non-public information "on September 8, 1999, at [his] home, during a conversation in which [the defendant] asked his son, Roger, for investment advice"); SEC v. Ballesteros Franco, 253 F. Supp. 2d 720, 724 (S.D.N.Y. 2003) (holding that complaint satisfied Rule 9(b) where it alleged that defendant was advised at a June 5, 1999 board meeting of an upcoming tender offer and then "between June 18 and June 24, [the defendant], along with his brother," used that non-public information to purchase 216,300 shares of stock). In the absence of any such particularized allegations, the complaint should be dismissed.

III. IN THE ALTERNATIVE, THE COURT SHOULD DIRECT THE PLAINTIFF TO PROVIDE A MORE DEFINITE STATEMENT

Under Rule 12(e) of the Federal Rules of Civil Procedure, a defendant "may move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response." Fed. R. Civ. P. 12(e). As a counterbalance to Rule 8(a)'s simplified pleading requirements, Rule 12(e) allows a defendant to request a more definite statement if the complaint fails to specify the allegations in a

manner that provides sufficient notice. Swierkiewicz v. Sorema N.A., 534 U.S. 506, 513-14, 122 S. Ct. 992, 998-99 (2002). As detailed above, see pp. 6 n.3, 7 n.4, supra, the SEC has omitted significant identifying information from its complaint. Without any specific indication as to when, where, or to whom in particular various alleged statements were made by Mr. Crombie, it is impracticable for him to provide an answer and either admit or deny those allegations.

CONCLUSION

For the foregoing reasons, this Court should dismiss the complaint under Fed. R. Civ. P. 9(b) for failure to allege facts giving rise to a strong inference of scienter or to plead fraud with particularity, or, in the alternative, direct the SEC to provide a more definite statement of its allegations under Fed. R. Civ. P. 12(e).

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Respectfully submitted,

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